UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/449,854	11/26/1999	Maria Grazia Pau	4240US	6774

24247 7590 08/08/2005

TRASK BRITT
P.O. BOX 2550
SALT LAKE CITY, UT 84110

EXAMINER	
HILL, MYRON G	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 08/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/449,854	PAU, MARIA GRAZIA	
	Examiner	Art Unit	
	Myron G. Hill	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 October 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 25-52* is/are pending in the application.

4a) Of the above claim(s) *30-34 and 39-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-17,25-29 and 35-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Examiner of your application has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1648, Examiner Hill.

Election/Restrictions

Claims 3-34, and 36-52 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on October 1, 2001.

The elected group I, claims 1-17, 25-29, and 35-38 are under consideration.

Specification

Claims 18-24 are canceled by the amendment 11/26/1999. In future listings of the claims they should be listed as "canceled".

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17, 25-29, and 35-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear what the metes and bounds of "functional derivative", "analogue", "derived", and "fragment" are.

It is not clear in claim 5 how the cell can be "primary" after it is transformed.

Claims 25-29 are not clear because they refer to "process" and that is not a statutory class of invention. The claims refer to improvement, but it is not clear what is improved, a product or a method. The claims refer to "using" and "wherein a cell is infected", but these are not positive recitations of method (using refers to qualities of a product and wherein a cell, is latent, not active such as infecting a cell). The claims are treated as methods because they seen to be drawn to a similar method as recited in claim 1.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-17, 25-29, and 35-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of

growing influenza virus in PER.C6 cell, does not reasonably provide enablement for "functional derivative", "analogue", "derived", and "fragment" of E1 and E2A or other viruses and other cell types. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The instant claims are evaluated for scope of enablement based on the Wands analysis. Many of the factors regarding undue experimentation have been summarized in *In re Wands*, 858 F.2d 731,8 USPQ2d 1400 (Fed.Circ.1988) as follows:

(1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

In the instant case, other than a method for growing influenza on PER.c6 cells, no other cells or viruses are shown.

There is no evidence or guidance or directions how to grow other viruses or use other cell types.

Influenza is well known in the art to adapt to growth in eggs and that proper processing of viral proteins is required for antigenicity and that influenza does not grow equally well in all cell types (Schultz-Cherry et al., page 3718, column 1). Furthermore, it is well known that viruses for vaccine purposes need

to be grown in an acceptable cell line and that all viruses do not grow equally well in all cell types.

The enabling disclosure is clearly not commensurate in scope with these claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Clearly there is lack of guidance directing a skilled artisan to practice the instantly claimed methods. Without specific guidance or direction and /or working examples, one of ordinary skill in the art would not be able to reproducibly practice the entire scope of the invention as claimed, without undue experimentation.

Claims 17 and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim is drawn to a range of viruses to be used in the method of claim 1 and purification by chromatography.

The specification provides examples of influenza virus and the cell type is known in the prior art to grow adenovirus. The specification does not provide enough examples from the list to provide written support for the list of viruses

claimed. The specification does not provide examples of the chromatographic columns and methods needed to purify the range of viruses.

Claim 13 is rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is not enabling for the said claims. The claim requires a specific deposited cell. Deposit of the cell would satisfy the enablement requirements of 35 U.S.C. 112.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that **all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent,** would satisfy the deposit requirements. See 37 CFR 1.808.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 6, 14, 15, 17, 25, and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Manservigi *et al.*

The claims are drawn to a method producing a viral protein that is not adenoviral in a cell with an E1 gene or function.

Manservigi *et al.* teach production of a viral glycoprotein (HSV gB) in 293 cells (Figure 2).

293 cells are immortalized with the E1 region of adenovirus 5 and the cells produce no adenoviral structural proteins. 293 cells contain part of pIX but it has not been shown to produce that protein.

Thus, Manservigi *et al.* anticipate the invention as claimed.

Claims 25-29 are rejected under 35 U.S.C. 102(b) as being anticipated by WO97/00326.

The claims are drawn to an improvement comprising a cell with an E1 region and optionally E2a or tsE2a. The claim is not clear if it is a product or method because there are no positive method steps and the claims recite qualities of a product. The claims are treated as product in this rejection.

WO97/00326 teaches a cell that expresses E1 and E2 (ts and normal) that is derived from a primary cell and is a clone called PER.C6. (claims 11 and 13, and Table 2).

Thus, WO97/00326 anticipate the claimed invention.

Claims 1-3, 5, 6, 14, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Massie *et al.* (US 5518913).

The claims are drawn to a method producing a viral protein that is not adenoviral in a cell with an E1 gene or function. The claims do not exclude the use of adenoviral vectors because the claims are drawn to producing a non-adenoviral virus or non-adenoviral protein and also wherein the cells do not produce adenoviral structural proteins.

Massie *et al.* teach production of a transgene in a cell (293) immortalized with the E1 region of adenovirus 5 that produces no adeno structural proteins (Examples 3 and 4). The transgenes were isolated and examined for amount produced.

Thus, Massie *et al.* anticipate the invention as claimed.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-17, 25-29, and 35-38 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6855544. The claimed invention finds support in the provisional application filed 4/15/99.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C.

102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The claims are drawn to producing non-adenovirus virus or proteins in a cell containing E1 and or E2.

Both sets of claims are based on using PER.c6 cells to produce non-adenoviral proteins. PER.c6 cells comprise the E1/E2 regions and variants thereof.

Thus, U.S. Patent No. 6855544 anticipates the claimed invention.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 8:30 am-5 pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Myron G. Hill
Patent Examiner
18 July 2005

JAMES HOUSEL 7/25/05
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600